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EXAMINER
PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
3738	

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Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary	Application No. 09/242,103	Applicant(s) ASIUS ET AL.	
	Examiner Paul B. Prebilic	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-52* is/are pending in the application.

4a) Of the above claim(s) *36 and 42-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-35 and 37-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *36,42 and 43* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Newly submitted claims 44-52 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

They are directed to a method of making (claims 44-46 and 50), a vial (claims 48 and 49) and a kit (claims 51 and 52), which are independent from the implant as originally set forth

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 44-52 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 21-36 and 37-41, drawn to the injectable implant, classified in class 623, subclass 23.58.

II. Claims 36 and 42-43, drawn to a freeze-dried product, classified in class 523, subclass 113.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as a breast implant filler

where it would be hydrated via body fluid after implantation and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Burton Amernick a provisional election was made with traverse to prosecute the invention of Group I, claims 21-35 and 37-41. Affirmation of this election must be made by applicant in replying to this Office action. Claims 36, 42, and 43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-35 and 37-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added language "materials of non-animal origin" or equivalent lacks original support and does not appear to be originally contemplated by Applicants. Rather, materials of many origins were originally disclosed without a distinction of source. It does not appear that the source of the material was important to the Applicants at the time the application was filed.

With regard to claim 41, "pluronic acid" is not adequately defined and the Examiner can find no definition for it. However, it appears that it is a trademark or tradename. If it is a trademark or tradename, it should be capitalized and accompanied by generic terminology so as to respect the propriety of the trademark. The Examiner will interpret this term as meaning "Pluronic" the surfactant of polyoxyethylene-polyoxypropylene block copolymer; see column 5 of Sander (US 5,356,629).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-35 and 37-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims language to materials of "non-animal origin" at least lacks antecedent basis from the specification even if it could be shown to have original support. Furthermore, it is not clear what constitutes a material of animal origin and what does not. For example, it does not appear to preclude materials made synthetically even if that material was originally naturally produced in an animal.

With regard to claim 41, "pluronic acid" appears to be a trademark and not proper for claim language because it is a source of the material and not the material itself. For this reason, the claim language is considered to be indefinite.

Specification

The disclosure is objected to because of the following informalities:

The meaning and chemical structure of "apyrogenic mannitol" is not defined so it is unclear how to interpret this language.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 21, 24, 27-31, 34, 35, and 37-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Ron et al (US 5,597,897) wherein the gel as claimed is the sequestering agent (e.g. CMC) or osteogenic protein together of Ron et al and the microparticles as claimed are the polymeric particles of Ron et al; see the entire document.

Since the sequestering agent of Ron et al is made of the same material (e.g. CMC) in the same percentage as claimed, it must be a gel to the extent that such language can be given patentable weight.

Since the osteogenic protein of Ron can theoretically be made synthetically by a protein synthesizer machine, which make the protein by amino acid addition reactions.

With regard to claim 24, the range of "about 150 to 850 microns" of Ron meets the claim language of 5 to less than 150 because of the "about" language in the disclosed range.

With regard to claims 30 and 31, the intrinsic viscosity is a function of both the polymer concentration and its molecular weight. Since the polymer concentration and solvent used is not specified, the claim limitation of intrinsic viscosity is quite broad. Furthermore, Ron et al discloses polymers of the same molecular weight range, but has

not measured or determined the intrinsic viscosity thereof even though this property is inherently present therein. For this reason, the Examiner hereby asserts that the intrinsic viscosity of the Ron polymers is within the claimed range and hereby burdens the applicants to show otherwise via comparative testing thereof.

With regard to claim 36, Applicants are directed to Example 4 of Ron et al.

With regard to claims 36-40, the surfactant, which is an agent that reduces the surface tension of the aqueous mixture, is met by the additives of Ron such as dextran sulfate, esters, or heparin.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 26, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ron et al (US 5,597,897) alone.

With regard to claim 26, Ron et al does not disclose the biodegradation time as claimed. However, Ron et al does specify that increasing the molecular weight does increase the biodegradation time, see column 3, lines 54-58. Therefore, it is the Examiner's position that it would have been obvious to change the molecular weight to adjust the biodegradation time in order to allow time for natural tissue replacement in different parts of the body. In addition, since biodegradation time is an inherent feature

of the polymer, the Applicants are hereby burdened to show that the claimed biodegradation time of Ron et al is outside the claimed range.

With regard to claims 32 and 33, the residual monomer and solvent amount are not specified by Ron et al. However, since these measured properties are present in Ron et al to some extent, the Examiner hereby burdens Applicants to show that the amount present in the Ron et al material is outside the claimed range via comparative testing.

Claims 21-25 and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scopelianos et al (EP 0711794) in view of Orly et al (WO 93/13755). Scopelianos meets the claim language except fails to disclose a gelation material for the liquid portion; see the entire document. However, Orly teaches that the use of a gelation material was known to the art; see the abstract. Hence, it is the Examiner's position that it would have been obvious to use the gelation material with other liquid components of Scopelianos to form a gel for the same reasons that Orly does the same and in order to improve the injection properties.

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ron et al in view of Sander et al (US 5,356,629). Ron et al meets the claim language except for the type of surfactants claimed. Sander, however, teaches that it was known to add "Pluronic" to similar implant materials; see column 5, lines 42-60. Hence, it is the Examiner's position that it would have been obvious to incorporate Pluronic into the Ron material for the same reasons that Sander does the same.

Response to Arguments

Applicant's arguments with respect to claims 21-36 have been considered but have been addressed in the Ron et al rejections by explanations set forth therein.

In response to applicant's arguments against the references individually, particularly Scopelianos and Orly, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Orly has collagen present therein, but since collagen can be made synthetically, it can be interpreted as falling within the scope of materials of non-animal origin.

Scopelianos is traversed because of the epsilon-caprolactone units in the polymer. However, since the polymers of Scopelianos can have lactic acid or glycolic acid units therein, one can reasonably call them lactic or glycolic acid polymers.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9301.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

Paul Prebilic
Primary Examiner
Art Unit 3738